continuance of the investigational study or the withdrawal of the exemption as soon as possible but in no event later than 5 days after such action.

(c) The sponsor shall notify each investigator if an application for premarket approval of the device under section 515 of the act is approved.

§ 813.50 Promotion and sale of intraocular lenses.

(a) Neither the sponsor nor any person acting for or on behalf of the sponsor shall disseminate any promotional material representing that the lens being investigated is safe and effective for the purposes for which it is under investigation. This requirement does not restrict the full exchange of scientific information concerning the device, including dissemination of scientific findings. However, this requirement prohibits promotional claims by the sponsor that the lens is safe and effective while the device is being investigated to establish its safety and effectiveness.

(b) The sponsor of the study of an intraocular lens may distribute the lens only if the sponsor has an effective exemption under this part for all lenses sold, and all patients who receive a lens are included in an investigational study under an exemption.

Subpart D—Institutional Review Committee

§ 813.60 Requirement of institutional review committee.

An institutional review committee shall review and monitor all investigational studies of an intraocular lens, except that where an institutional review committee does not exist and one cannot be established, the sponsor of the study shall submit the investigational plan and report of prior investigations pursuant to §813.20(b) (5) and (6) for review by the Food and Drug Administration. The Food and Drug Administration may disapprove a study that is not to be reviewed and monitored by an institutional review committee if, in the opinion of the Commissioner, the lack of institutional review committee review may expose human subjects to undue risk.

§ 813.62 Membership of an institutional review committee.

(a) Any institutional review committee that undertakes to participate in the review of a proposed study shall possess the professional competence necessary to review the specific study. An institutional review committee shall be composed of not less than five individuals with varying backgrounds to assure complete and adequate review of the investigational study. Such committee shall include, in addition to persons possessing the professional competence necessary to review scientific activities, persons whose primary concerns are in nonscientific areas, e.g., lawyers, clergymen, ethicists, social scientists, or other lay persons. No such committee shall consist entirely of members of a single professional group.

(b) The records of a committee shall identify each member by name, earned degrees, positions or occupation, representative capacity, and other pertinent indications of experience, such as board certification or licenses, sufficient to describe each member's chief anticipated contributions to such committee's deliberations. The employment or other relationship between each member and the institution and any investigator or sponsor of any investigational study reviewed and monitored by the committee shall be described in the records of the committee, e.g., full-time employee, part-time employee, member of governing panel or board, paid consultant, or unpaid consultant.

(c) No committee shall consist entirely of persons who are officers, employees, or agents of, or are otherwise associated with, the institution, apart from their membership on the committee.

(d) No member of a committee shall participate in the committee's review of monitoring of an investigational study in which he has a conflicting interest. No investigator or sponsor shall participate in the selection of members for a committee that will review his investigational study.

(e) The committee is responsible for determining whether a member has a conflict of interest and, if so, such

member shall not participate in the review or monitoring of the study.

(f) An institutional review committee may in its discretion invite persons with competence in particular areas (consultants) to assist in the review of complex issues whose resolution requires expertise beyond or in addition to that available within the committee. Consultants may not vote.

§ 813.65 Procedures for review and monitoring of investigational studies by an institutional review committee.

(a) An institutional review committee shall follow written procedures adopted by either the committee or the institution for conducting its review and monitoring of investigational studies and for reporting its findings to the institution, the sponsor, and the investigator.

(b) A committee shall conduct business by a quorum, which shall be defined by written procedures. In no event shall a quorum be less than a majority of the members of the committee.

(c) A committee participating in the review of an investigational study shall monitor that study until the investigation is completed or discontinued by the sponsor or terminated or suspended by the committee or an exemption is withdrawn by the Food and Drug Administration.

§ 813.66 Procedures and criteria for review of investigational studies by an institutional review committee.

(a) Upon receipt of the proposed investigational study, including an investigational plan and a report of prior investigations of the lens from the sponsor or investigator, a committee that is to participate in the review of the study shall perform the following functions:

(1) Determine that each investigator has sucessfully completed a residency in ophthalmology or its documented equivalent, and is licensed to practice medicine in the State or country in which the investigational study is to take place.

(2) Review the investigational plan and determine that the nature of the investigational study provides a benefit to the proposed subjects such that the risks to the subjects are justified.

(3) Assure that sufficient records will be kept so as to describe clearly the results of the study.

(4) Require the investigator to notify the institutional review committee of any unanticipated side effects or increased hazards, or any changes in the investigational study, actual or proposed, that have resulted or may result from the preliminary findings of the study that could result in modification or reversal of the initial determination to authorize beginning the study.

(5) Monitor the investigational study at intervals appropriate to the degree of risk but in no event exceeding 1 year so as to assure that the study continues to be justified during the course of the study.

(6) Assure that the rights of human subjects are properly protected, that legally effective informed consent is obtained, and that the method of obtaining consent properly informs the human subject of the significant aspects of the study in accordance with Part 50 of this chapter.

(7) Receive, process, and act on complaints relating to any study under review, e.g., from subjects, sponsor, and other members of an institution's staff.

(b) If the committee has any question regarding the proposed investigational study, the committee may request the investigator or sponsor to submit additional information concerning the proposed study.

(c) The committee shall review and approve, approve with modifications, or disapprove a proposed study as soon as possible after receipt thereof.

(d) The committee may disapprove a proposed study for any reason it considers appropriate and shall disapprove a proposed study if it makes any of the following findings:

(1) The information submitted to the committee concerning the study contains an untrue statement of a material fact or omits material information required by this part.

(2) The report of prior investigations of the lens is inadequate to support a conclusion that it is reasonably safe to begin the proposed investigational study.